

# AMERICAN PREVENTIVE MEDICAL ASSOCIATION

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May 28, 1999

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Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, Maryland 20852

RE: Docket No. 98-N-1265

Food and Drug Modernization Act of 1997

Section 127, Application of Federal Law to Practice of Pharmacy

Compounding.

Federal/State Memorandum of Understanding on Interstate Distribution of  
Compounded Drug Products; Draft

Dear Dockets Management Branch:

I am writing on behalf of the American Preventive Medical Association, a nonprofit advocacy organization with members in 47 states and 7 foreign countries. We are dedicated to creating a health care environment in which practitioners can practice in good conscience, with the well-being of their patients foremost in their minds, without fear of censure or recrimination for the use of complementary and alternative therapies.

A large majority of our physicians use the services of compounding pharmacies for such products as injectable B-Complex, thiamine, and taurine. They use compounded products for patients with special health needs, and for patients who don't respond to commercial, mass-market medications. The draft Memorandum of Understanding jeopardizes patient access to such products by strictly limiting the amount of prescriptions compounding pharmacies may ship interstate.

While we understand the agency's interest in regulating the manufacturing of drugs in order to protect consumers, we believe that equally effective and less draconian measures can be found to insure that compounding pharmacies do not engage in manufacturing without doing so at the expense of patients with special needs. The draft MOU is unclear, severely limits competition, unfairly penalizes small pharmacies and those in less populous states, and amounts to restraint of trade. Specifically:

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- Faced with seemingly arbitrary limits of 5 and 20 percent, depending on their location, compounding pharmacies will be forced to predict their prescriptions sales for the year.
- It is unclear whether or not the MOU prohibits/restricts prescriptions "For Office Use."
- The 5 and 20 percent figures seem arbitrary and unnecessary, especially if the purpose of setting such ceilings is to enable inspectors to distinguish between manufacturing and compounding.
- How will the ceilings affect mail order pharmacies and those with offices in multiple states?
- Why do the ceilings pertain only to interstate shipments? Most pharmacies that provide only compounded products will not be able to generate enough intrastate prescriptions to meet the MOU requirements.
- Large, established businesses will have a distinct advantage over small, new pharmacies.
- The ceilings have the potential to obstruct the physician-pharmacist relationship that is necessary to help patients with special needs. Our members fear being told that their compounding pharmacist has reached his limit for a particular drug and, that if he compounds for their patients, the FDA will find him in violation of the law.

We believe that the intent of Congress was to ensure that patients would continue to have access to compounded medications that are lawfully prescribed by their physicians. The draft MOU runs counter to that intent, and creates barriers to access that do not presently exist. We recommend eliminating the artificial limits on interstate shipments, and encourage the agency to look instead to creating a more flexible, fair system to distinguish between compounding and manufacturing. According to numerous court cases, the government should use the least restrictive means possible to achieve its ends. Impeding access to life-saving and life-enhancing drugs for patients with special needs, under the guise of consumer protection, is simply unjustifiable.

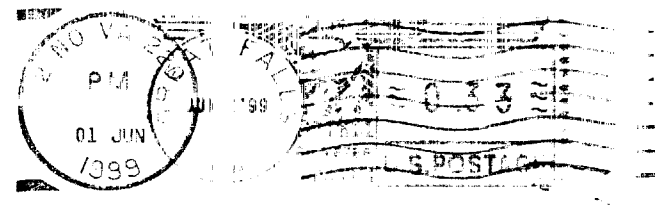
Sincerely,



Ralph A. Miranda, M.D.  
President



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